- 493.1471 Standard; Cytology general supervisor responsibilities.
- 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.
- 493.1483 Standard; Cytotechnologist qualifications.
- 493.1485 Standard; Cytotechnologist responsibilities.
- 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
- 493.1489 Standard; Testing personnel qualifications.
- 493.1491 Technologist qualifications on or before February 28, 1992.
- 493.1495 Standard; Testing personnel responsibilities

Subparts N-P [Reserved]

Subpart Q—Inspection

- 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.
- 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.
- 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.
- 493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.
- 493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation

Subpart R—Enforcement Procedures

- 493.1800 Basis and scope.
- 493.1804 General considerations.
- 493.1806 Available sanctions: All laboratories.
- 493.1807 Additional sanctions: Laboratories that participate in Medicare.
- 493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.
 493.1809 Limitation on Medicaid payment.
- 493.1810 Imposition and lifting of alternative sanctions.
- 493.1812 Action when deficiencies pose immediate jeopardy.
- 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.
- 493.1816 Action when deficiencies are not at the condition level.
- 493.1820 Ensuring timely correction of deficiencies.
- 493.1826 Suspension of part of Medicare payments.
- 493.1828 Suspension of all Medicare payments.

- 493.1832 Directed plan of correction and directed portion of a plan of correction.
- 493.1834 Civil money penalty.
- 493.1836 State onsite monitoring.
- 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.
- 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.
- 493.1842 Cancellation of Medicare approval.
- 493.1844 Appeals procedures.
- 493.1846 Civil action.
- 493.1850 Laboratory registry.

Subpart S [Reserved]

Subpart T—Consultations

493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

Source: 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

Subpart A—General Provisions

Source: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

§ 493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in §493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—